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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,282	07/07/2003	David B. MacLean	PC9517H	8230

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PFIZER INC.
PATENT DEPARTMENT, MS8260-1611
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EXAMINER	
WEDDINGTON, KEVIN E	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 08/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/615,282	MACLEAN ET AL.	
	Examiner	Art Unit	
	Kevin E. Weddington	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10-31-03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 1-22 are presented for examination.

Applicants' preliminary amendment filed July 7, 2003 and the information disclosure statement filed October 31, 2003 have been received and entered.

In claim 1, line 1, the word "suscptible" and line 12, the word "effectiv"; and in claim 7, line 1, the word "senil" are misspelled. Corrections are required.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-3 and 11 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-3 of prior U.S. Patent No. 6,403,611.

Both the present application and the patented application are claiming the same invention:

A method of inhibiting a pathological condition which is susceptible or partially susceptible to inhibition by an estrogen, antiestrogen or estrogen agonist which comprises administering to a mammal in need of inhibition of decrease libido and effective amount of a compound of formula I.

This is a double patenting rejection.

Claims 1-3 and 11 are not allowed.

Claims 1-3 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 3-5 of prior U.S. Patent No. 6,613,796.

The present application and the patented application are claiming the same invention:

A method of inhibiting incontinence which comprises administering to a mammal in need of inhibition of incontinence with an effective amount of a compound of formula I.

This is a double patenting rejection.

Claims 1-3 are not allowed.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,107,331. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present application teaches a method of inhibiting a pathological condition which is susceptible or partially susceptible to

inhibition by an estrogen, antiestrogen or estrogen agonist which comprises administering to a mammal in need of inhibition of said pathological condition selected from adjuvant breast cancer, breast disorders, and male breast cancer with effective amount of a compound of formula I; and the present application teaches a method of inhibiting or treating a pathological condition of the breast that is selected from the group consisting of galactorrhea, gynecomastia, hypertrophy, polythelia, etc.. with an effective amount of (-)-Cis-6-phenyl-5-[4-(2-pyrrolidin-1-yl-ethoxy)-phenyl]5,6,7,8-tetrhydronaphthalen-2-ol, (a compound derived from formula I). Clearly, the present application's breast disorders encompass the patent application's specific types of breast disorders (breast cancer).

Claims 1-4 are not allowed.

Claims 1-3 and 5 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,274,618. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present application teaches a method of inhibiting a pathological condition which is susceptible or partially susceptible to inhibition by an estrogen, antiestrogen or estrogen agonist which comprises administering to a mammal in need of inhibition of said pathological condition selected from vaginal atrophy with an effective amount of a compound of formula I; and the patented application teaches a method for inhibiting vaginal atrophy that comprises administering to a patient in need of inhibition of said condition an effective amount of (-)-Cis-6-phenyl-5-[4-(2-pyrrolidin-1-yl-ethoxy)-

phenyl]5,6,7,8-tetrhydronaphthalen-2-ol, (a compound derived from formula I). Clearly, the present application's compounds of formula I encompass the patent application's specific active ingredient derived from the same formula I.

Claims 1-3 and 5 are not allowed.

Claims 1-4 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,911,456. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present application teaches a method of inhibiting a pathological condition which is susceptible or partially susceptible to inhibition by an estrogen, antiestrogen or estrogen agonist which comprises administering to a mammal in need of inhibition of said pathological condition selected from adjuvant breast cancer, breast disorders, and male breast cancer with effective amount of a compound of formula I; and the patented application teaches a method of reducing the occurrence of breast cancer in a mammal after primary treatment, the method comprising administering to a mammal in need of adjuvant therapy for breast cancer a therapeutically effective amount of a compound of formula I. Clearly, the present application's inhibition of breast disorders inherently reduces the occurrence of breast cancer in the absence of evidence to the contrary.

Claims 1-4 are not allowed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In this regard, the application disclosure and claims have been compared per factors indicated in the decision In re Wands, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation.

The factors include:

1) the quantity of experimentation necessary

2) the amount of direction or guidance provided

3) the presence or absence of working examples

4) the nature of the invention

5) the state of the art

6) the relative skill of those in the art

7) the predictability of the art and

8) the breadth of the claims

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice that instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to a method the present application teaches a method of inhibiting a pathological condition which is susceptible or partially susceptible to inhibition by an estrogen, antiestrogen or estrogen agonist which comprises administering to a mammal in need of inhibition of said pathological condition selected from uterine cancer, adjuvant breast cancer, breast disorders, male breast cancer, migraine, incontinence, vaginal atrophy, bladder infection, senile gynecomastia, diabetes, hyperglycemia, failure of wound healing, melanoma, impotence, etc.. with effective amount of a compound of formula I;

The relative skill of those in the art is generally that of a Ph.D. or M.D.

The present invention is unpredictable unless experimentation is shown for the compounds of formula I can inhibit the said pathological conditions of disclosed in claims 1 and 4-22.

The breadth of the claims

The claims are very broad and inclusive to all compounds derived from formula I disclosed in claim 1.

The amount of direction or guidance provided and the presence or absence of working examples

There are no working examples showing the instant compounds derived from formula I will, in fact, inhibit the pathological conditions set forth in claims 1 and 4-22. The specification only shows assays stating broadly the compounds of formula I

may inhibit the said pathological conditions by hind-insight since the compounds are known as estrogen antagonists and estrogen agonists which are known to treat the said conditions.

The quantity of experimentation necessary

Applicants have failed to provide guidance as to how the all the compounds derived from formula I will be effective in inhibiting the said pathological conditions of claims 1 and 4-22; therefore, undue experimentation would be required to practice the invention as it is claimed in its current scope.

Claims 1-22 are allowed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Cameron et al. (5,552,412).

Cameron et al. teach a method for treating or preventing breast cancer by administering a pharmaceutical composition containing an effective amount (0.25 mg to 25 mg) of a compound derived from formula I which is the same formula I as applicants. Note particularly column 15, lines 45-48 teaches that the compounds are antiestrogens in breast tissue and therefore would be useful in treating and

preventing (inhibiting) breast cancer. Clearly, the cited reference anticipates applicants' instant invention; therefore, the instant invention is unpatentable.

Claims 1-4 are not allowed.

The remaining references listed on the enclosed PTO-892 are cited to show the state of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 11:00 am-7:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kevin E. Weddington
Primary Examiner
Art Unit 1614

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August 10, 2005